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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/068,812	02/04/2002	Richard J. Greff	034298-122	8436

7590 09/02/2004

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EXAMINER	
GHALI, ISIS A D	

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 09/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/068,812	GREFF, RICHARD J.	
	Examiner	Art Unit	
	Isis Ghali	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 July 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *9/25/03, 7/2/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The receipt is acknowledged of applicants' IDS, amendment, and request under 1.114, all filed 07/02/2004.

Claims 1-17 are included in the prosecution.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 07/02/2004 has been entered.

Double Patenting

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double

patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claims 1, 15 and 16 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 8 of U.S. Patent No. 6,162,192, now on US '192, in view of US 6,063,061 for Wallace et al., now on US '061. The present claim 1 is directed to hemostatic composition comprising crosslinked gelatin and wetting agent, claim 15 is packaged sterilized composition, and claim 16 is kit comprising syringe, non-hydrated pledget consisting of crosslinked gelatin and wetting agent. The US '192 patent claims composition comprising syringe and pledget and hydrating agent. The difference between the present claims and the previously issued conflicted claim is that the issued claim does not teach the sterilized packaged composition, or the pledget made of crosslinked gelatin. US '061 teaches a biocompatible hemostatic composition comprising non-hydrated cross-linked gelatin and hydrating agent (col.3, lines 4-6, 43, 67; col.4, lines 11-12, 41-42; col.5, line 40; col.8). The composition can be in the form of sterile packaged kit comprising the non-hydrated gelatin and the hydrating agent that applied through a syringe (col.5, lines 6-10, 25-35; col.8, lines 32-36). The reference teaches that the non-hydrated crosslinked gelatin is advantageous because it swells to its full equilibrium swell value which is valuable in hemostasis and inhibiting tissue adhesion (col.3, lines 5-7; col.8, lines 10-14). Thus, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide a hemostatic composition and kit comprising pledget and hydrating

agent as claimed by US '192, and select crosslinked gelatin in a sterile package as disclosed by US '061, motivated by the teaching of US '061 that the non-hydrated crosslinked gelatin is advantageous because it swells to its full equilibrium swell value which is valuable in hemostasis and inhibiting tissue adhesion, with reasonable expectation of having a sterile packaged composition or kit comprising non-hydrated crosslinked gelatin and hydrating agent that provide excellent hemostasis. Thus, the present claims are obvious over the issued claim 8 of the commonly assigned US '192 in view of US '061.

4. Claims 1, 15 and 16 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 6-18 of U.S. Patent No. 6,200,328, now on US '328, in view of US 6,063,061 for Wallace et al., now on US '061. The present claim 1 is directed to hemostatic composition comprising crosslinked gelatin and wetting agent, claim 15 is packaged sterilized composition, and claim 16 is kit comprising syringe, non-hydrated pledget consisting of crosslinked gelatin and wetting agent. US '328 claims system, reads on kit, comprising pledget and hydrating fluid and syringe. The difference between the present claims and the previously issued conflicted claims is that the issued claims do not teach the sterilized packaged composition, or the pledget made of crosslinked gelatin. US '061 teaches a biocompatible hemostatic composition comprising non-hydrated cross-linked gelatin and hydrating agent (col.3, lines 4-6, 43, 67; col.4, lines 11-12, 41-42; col.5, line 40; col.8). The composition can be in the form of sterile packaged kit comprising the non-hydrated

gelatin and the hydrating agent that applied through a syringe (col.5, lines 6-10, 25-35; col.8, lines 32-36). The reference teaches that the non-hydrated crosslinked gelatin is advantageous because it swells to its full equilibrium swell value which is valuable in hemostasis and inhibiting tissue adhesion (col.3, lines 5-7; col.8, lines 10-14). Thus, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide a hemostatic composition and kit comprising pledget and hydrating agent as claimed by US '328, and select crosslinked gelatin in a sterile package as disclosed by US '061, motivated by the teaching of US '061 that the non-hydrated crosslinked gelatin is advantageous because it swells to its full equilibrium swell value which is valuable in hemostasis and inhibiting tissue adhesion, with reasonable expectation of having a packaged sterile composition or kit comprising non-hydrated crosslinked gelatin and hydrating agent that provide excellent hemostasis. Thus, the present claims are obvious over the issued claims 6-18 of the commonly assigned US '328 in view of US '061.

5. Claims 1, 15 and 16 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5, 12-16 of U.S. Patent No. 6,440,151, now on US '151, in view of US 6,063,061 for Wallace et al., now on US '061. The present claim 1 is directed to hemostatic composition comprising crosslinked gelatin and wetting agent, claim 15 is packaged sterilized composition, and claim 16 is kit comprising syringe, non-hydrated pledget consisting of crosslinked gelatin and wetting agent. US '151 claims system, reads on kit, comprising pledget and

hydrating fluid and syringe. The difference between the present claims and the previously issued conflicted claims is that the issued claims do not teach the sterilized packaged composition, or the pledget made of crosslinked gelatin. US '061 teaches a biocompatible hemostatic composition comprising non-hydrated cross-linked gelatin and hydrating agent (col.3, lines 4-6, 43, 67; col.4, lines 11-12, 41-42; col.5, line 40; col.8). The composition can be in the form of sterile packaged kit comprising the non-hydrated gelatin and the hydrating agent that applied through a syringe (col.5, lines 6-10, 25-35; col.8, lines 32-36). The reference teaches that the non-hydrated crosslinked gelatin is advantageous because it swells to its full equilibrium swell value which is valuable in hemostasis and inhibiting tissue adhesion (col.3, lines 5-7; col.8, lines 10-14). Thus, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide a hemostatic composition and kit comprising pledget and hydrating agent as claimed by US '151, and select crosslinked gelatin in a sterile package as disclosed by US '061, motivated by the teaching of US '061 that the non-hydrated crosslinked gelatin is advantageous because it swells to its full equilibrium swell value which is valuable in hemostasis and inhibiting tissue adhesion, with reasonable expectation of having a packaged sterile composition or kit comprising non-hydrated crosslinked gelatin and hydrating agent that provide excellent hemostasis. Thus, the present claims are obvious over the issued claims 6-18 of the commonly assigned US '328 in view of US '061.

6. Claims 1, 15 and 16 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5, 12-16 of U.S. Patent No. 6,527,734, now on US '734, in view of US 6,063,061 for Wallace et al., now on US '061. The present claim 1 is directed to hemostatic composition comprising crosslinked gelatin and wetting agent, claim 15 is packaged sterilized composition, and claim 16 is kit comprising syringe, non-hydrated pledget consisting of crosslinked gelatin and wetting agent. US '734 claims system, reads on kit, comprising pledget and hydrating fluid and syringe. The difference between the present claims and the previously issued conflicted claims is that the issued claims do not teach the sterilized packaged composition, or the pledget made of crosslinked gelatin. US '061 teaches a biocompatible hemostatic composition comprising non-hydrated cross-linked gelatin and hydrating agent (col.3, lines 4-6, 43, 67; col.4, lines 11-12, 41-42; col.5, line 40; col.8). The composition can be in the form of sterile packaged kit comprising the non-hydrated gelatin and the hydrating agent that applied through a syringe (col.5, lines 6-10, 25-35; col.8, lines 32-36). The reference teaches that the non-hydrated crosslinked gelatin is advantageous because it swells to its full equilibrium swell value which is valuable in hemostasis and inhibiting tissue adhesion (col.3, lines 5-7; col.8, lines 10-14). Thus, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide a hemostatic composition and kit comprising pledget and hydrating agent as claimed by US '734, and select crosslinked gelatin in a sterile package as disclosed by US '061, motivated by the teaching of US '061 that the non-hydrated crosslinked gelatin is advantageous because it swells to its full equilibrium swell value

which is valuable in hemostasis and inhibiting tissue adhesion, with reasonable expectation of having a packaged sterile composition or kit comprising non-hydrated crosslinked gelatin and hydrating agent that provide excellent hemostasis. Thus, the present claims are obvious over the issued claims 6-18 of the commonly assigned US '734 in view of US '061.

7. Claims 1, 15 and 16 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 8-22 of U.S. Patent No. 6,540,735, now on US '735, in view of US 6,063,061 for Wallace et al., now on US '061. The present claim 1 is directed to hemostatic composition comprising crosslinked gelatin and wetting agent, claim 15 is packaged sterilized composition, and claim 16 is kit comprising syringe, non-hydrated pledget consisting of crosslinked gelatin and wetting agent. US '735 claims system, reads on kit, comprising pledget and hydrating fluid and syringe. The difference between the present claims and the previously issued conflicted claims is that the issued claims do not teach the sterilized packaged composition, or the pledget made of crosslinked gelatin. US '061 teaches a biocompatible hemostatic composition comprising non-hydrated cross-linked gelatin and hydrating agent (col.3, lines 4-6, 43, 67; col.4, lines 11-12, 41-42; col.5, line 40; col.8). The composition can be in the form of sterile packaged kit comprising the non-hydrated gelatin and the hydrating agent that applied through a syringe (col.5, lines 6-10, 25-35; col.8, lines 32-36). The reference teaches that the non-hydrated crosslinked gelatin is advantageous because it swells to its full equilibrium swell value which is valuable in

hemostasis and inhibiting tissue adhesion (col.3, lines 5-7; col.8, lines 10-14). Thus, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide a hemostatic composition and kit comprising pledget and hydrating agent as claimed by US '735, and select crosslinked gelatin in a sterile package as disclosed by US '061, motivated by the teaching of US '061 that the non-hydrated crosslinked gelatin is advantageous because it swells to its full equilibrium swell value which is valuable in hemostasis and inhibiting tissue adhesion, with reasonable expectation of having a packaged sterile composition or kit comprising non-hydrated crosslinked gelatin and hydrating agent that provide excellent hemostasis. Thus, the present claims are obvious over the issued claims 6-18 of the commonly assigned US '735 in view of US '061.

8. Claims 1, 15, and 16 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 8-14, 17-22 of copending Application No. 10/366,752 in view of US 6,063,061 for Wallace et al., now on US '061. The present claim 1 is directed to hemostatic composition comprising crosslinked gelatin and wetting agent, claim 15 is packaged sterilized composition, and claim 16 is kit comprising syringe, non-hydrated pledget consisting of crosslinked gelatin and wetting agent. the potentially conflicted application claims system, reads on kit, comprising pledget and hydrating fluid and syringe. The difference between the present claims and the potentially conflicted claims is that the conflicted claims do not teach the sterilized packaged composition, or the pledget made of

crosslinked gelatin. US '061 teaches a biocompatible hemostatic composition comprising non-hydrated cross-linked gelatin and hydrating agent (col.3, lines 4-6, 43, 67; col.4, lines 11-12, 41-42; col.5, line 40; col.8). The composition can be in the form of sterile packaged kit comprising the non-hydrated gelatin and the hydrating agent that applied through a syringe (col.5, lines 6-10, 25-35; col.8, lines 32-36). The reference teaches that the non-hydrated crosslinked gelatin is advantageous because it swells to its full equilibrium swell value which is valuable in hemostasis and inhibiting tissue adhesion (col.3, lines 5-7; col.8, lines 10-14). Thus, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide a hemostatic composition and kit comprising pledget and hydrating agent as claimed by the conflicted claims, and select crosslinked gelatin in a sterile package as disclosed by US '061, motivated by the teaching of US '061 that the non-hydrated crosslinked gelatin is advantageous because it swells to its full equilibrium swell value which is valuable in hemostasis and inhibiting tissue adhesion, with reasonable expectation of having a packaged sterile composition or kit comprising non-hydrated crosslinked gelatin and hydrating agent that provide excellent hemostasis. Thus, the present claims are obvious over the conflicted claims of the commonly assigned application in view of US '061.

This is a provisional obviousness-type double patenting rejection.

Specification

9. The use of the trademark "Gelfoam", "Pluronic", "Tween", "Brij", "Myrj", "UCC Carbowax", "Span" and "PGE" have been noted in this application. They should be

capitalized wherever they appear and be accompanied by the generic terminology. The trademarks should be identified by capitalizing each letter of the mark in bracket or include the proper trademark symbol such as ^{TM} or ^{R} (in case of word or letter marks) or otherwise indicating the description of the mark (in the case of marks in the form of a symbol or device or other nontextual form). MPEP608.01(v).

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Rejections - 35 USC § 112

10. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

11. Claims 1-15 and 17 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The amendment to claims 1 and 5 to recite the wetting agent as a "liquid" introduced new matter because nowhere in the specification applicant has disclosed "liquid wetting agent". The wetting agents are listed in the specification on page 9, lines 3-13, with no mention of the physical status of the any of them.

Claim Rejections - 35 USC § 102

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

13. Claims 1, 15, and 16 are rejected under 35 U.S.C. 102(e) as being anticipated by US 6,063, 061 (061).

The present claim 1 recites composition comprising cross-linked gelatin and wetting agent. The composition is in form of sterilized and packaged sponge (claim 15). Claim 16 recites kit comprising syringe, non-hydrated crosslinked gelatin and hydrating agent.

US '061 disclosed a biocompatible hemostatic composition comprising non-hydrated cross-linked gelatin and hydrating agent (col.3, lines 4-6, 43, 67; col.4, lines 11-12, 41-42; col.5, line 40; col.8). The composition can be in the form of sterile packaged kit comprising the non-hydrated gelatin and the hydrating agent that applied through a syringe (col.5, lines 6-10, 25-35; col.8, lines 32-36).

The limitations of claims 1, 15, and 16 are met by US '061.

14. Claims 1-6, 8-13, 15, and 17 are rejected under 35 U.S.C. 102(e) as being anticipated by US PGPB 2002/0042378 ('378) with the effective filing date of June 10, 1999.

The present claim 1 recites composition comprising cross-linked gelatin and wetting agent. The claim recites the amount of the wetting agent intended to permit wetting of gelatin in the presence of an aqueous solution. The wetting agent is impregnated with (claim 2) or mixed with (claim 3) or coated on (claim 4) the gelatin. Claim 5 recites method for decreasing the hydration time of cross-linked gelatin composition comprises incorporating wetting agent with the gelatin prior to its hydration, i.e. prior to use, by mixing (claim 6), or coating the wetting agent into the gelatin (claim 8). The composition is bioabsorbable (claim 9). The composition further comprises : growth factor, thrombus enhancing agents or antimicrobial agents (claim 10). The wetting agent forms 0.1 to 10% of the gelatin (claim 11). Claim 12 recites the coating achieved by applying to the surface of the gelatin a solution consisting of the wetting agent and solvent in a concentration of 1-20%, then the solvent removed by evaporation of the solvent (claim 13). The composition is in form of sterilized and packaged sponge (claim 15).

PGPB '378 disclosed hemoactive material or composition that is suitable for inhibiting bleeding, i.e. hemostatic, and are delivered to the target region in the tissue subject to bleeding (page 2: 0012; page 5: 0039). The material comprises cross-linked biologically compatible polymer, non cross-linked biologically compatible polymer, and plasticizer (abstract; page 2: 0016). The most preferred cross-linked polymer is gelatin

(page 3: 0031; page 5: example 2). The non cross-linked polymers include cellulose derivatives, polyvinyl polymers, and polyoxyethylenes; and the plasticizers include polyethylene glycol and sorbitol (page 2: 0016, 0018), all disclosed by applicant in the first full paragraph of page 9 of the instant specification as wetting agents. The non cross-linked polymer solublizes when exposed to blood and releases the cross-linked polymer so that it can hydrate as it absorbs water from the blood, that reads on the intended function of the wetting agent (page 1: 0012). Decreasing the hydration time of the cross-linked gelatin that claimed in claim 5 is inherent in the material of the reference that comprises cross-linked gelatin and polyethylene glycol, and that has the wetting agent incorporated with the cross-linked gelatin prior to use and hydration. The cross-linked gelatin particles are dispersed in a solution comprising non cross-linked polymer and the polyethylene glycol and well mixed before drying as recited in claims 3 and 6; that also reads on impregnating the wetting agent with gelatin because the gelatin particles are suspended in the wetting agent as in claim 2; and reads on coating the wetting agent on the surface of gelatin because the particles of gelatin are surrounded by the suspension of the wetting agents as claimed in claims 4 and 8; and example 2 shows that the dispersion of the cross-linked and non cross-linked polymers and plasticizer is performed prior to the formation of the sponge, i.e. prior to foaming (page 1:0012; page 2: 0018; page 4: 0035; page 6: 0045). The cross-linked polymers are degradable, i.e. bioabsorbable as claimed in claim 9 (page2: 0013). The composition further comprising bioactive agents including blood clotting agents such as thrombin, antibiotics, bacteriostatic and bacteriocidal agents, and antiviral, that reads on

claim 10 (page 2: 0012; page 4: 0036). Example 2 of the reference shows that the amount of cross-linked gelatin in the composition is 1-4 grams, and the amount of polyethylene glycol is 0.1-2%, therefor, if the dispersion comprises 2 gm of gelatin that is to be 2000 mg in 100 ml and 1% of polyethylene glycol that is 100 mg per 100 ml, then the amount of polyethylene glycol is calculated to form 5 wt.% of the cross-linked gelatin, reads on the amount claimed in claim 11 (example 2: pages 5-6). The method of making the material of the reference includes dispersing the cross-linked gelatin particles in a solution comprising polyethylene glycol (wetting agents) in a concentration of 0.1-2% and well mixing the suspension before drying, i.e. before evaporating the solvent as in claims 12 and 13 (page 3: 0021; page 4: 0035; page 6: 0045).). The composition of the reference can be in the form of sponge (page 4: 0035) that is provided in sterile packs, as claimed in claim 15 (page 3: 0020).

The limitation of claims 1-6, 8-13 and 15 are met by PGPB '378.

Claim Rejections - 35 USC § 103

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

16. Claims 7 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over PGPB '378.

The teaching of the PGPB '378 is discussed under 102 rejection above.

However, the reference does not teach impregnating the gelatin with the wetting agent as in claim 7, or the amount of the wetting agent in the gelatin composition after evaporation of the solvent.

It is expected that if the cross-linked gelatin is in the porous form, then the wetting agent is added to the porous material and mixed, the porous material will be impregnated with the wetting agent. Since applicant not claiming any particular form of the cross-linked gelatin, thus, mixing would read on impregnated depending on the form of the gelatin used in the instant invention.

It is expected to one having ordinary skill in the art to adjust the drying and evaporation of the solvent in order to obtain the desired concentration of the wetting agent in the composition, and the claimed concentration of the wetting agent in claim 14 does not impart patentability to the claims, absent evident to the contrary.

Accordingly, it would have been obvious to one having ordinary skill in the art at the time of the invention to obtain a composition comprising cross-linked gelatin and wetting agent as disclosed by PGPB '378 and select the method of incorporating the wetting agent into the gelatin such as mixing, impregnating or coating depending on the form of the cross-linked gelatin, and adjust the degree of drying of the final product to achieve a desired concentration of the wetting agent in the composition, with reasonable expectation of success having a hemostatic composition that stop bleeding at the site of application within a reasonable time.

Response to Arguments

17. Applicant's arguments filed 07/02/2004 have been fully considered but they are not persuasive. The main gist of applicant argument against the rejection of claim 1-6, 8-13, 15 and 17 as being anticipated by PGPB '378 is that the wetting agent of the present invention is in aqueous form and incorporated with the gelatin to permit uniform wetting of the sponge and to facilitate the hydration of the sponge, while the reference disclosed dry non-cross-linked polymer.

In response to the above argument, the examiner position is the claims are directed to composition, and all the elements of the composition are disclosed by the reference. The wetting agents disclosed by applicants are the same agents disclosed by the reference under the non-cross-linked polymer. Applicants are not claiming any specific wetting agents and the term can read on any of the non-cross-linked polymers or the optional ingredients. In response to applicant's argument that the reference does not disclose that the wetting agent to permit the uniform wetting of the sponge and to facilitate its hydration, the examiner position is that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

18. With regard to the rejection of claims 7 and 14 under 35 U.S.C. 103(a) as being unpatentable over PGPB '378, applicant has failed to traverse the rejection and the response is considered to be acquiescence to the position taken by the examiner. The rejection is therefore repeated for reasons of record. See MPEP 37 CFR 1.111 (b).

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 7:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Isis Ghali
Examiner
Art Unit 1615

Isis Ghali

ISIS GHALI
PATENT EXAMINER